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Application No. 10/665,188
Filed: September 17, 2003
TC Art Unit: 1651
Confirmation No.: 5560AMENDMENT TO THE CLAIMS

1. (Withdrawn/Currently Amended) A method of preparing a mammalian amniotic membrane extract, said method comprising carrying out in the order given the steps of:

obtaining a healthy amniotic membrane from a pregnant mammal;
homogenizing said membrane to obtain a homogenate solution;
centrifuging said homogenate solution and removing the homogenate supernatant;

quick-freezing said homogenate supernatant; and

lyophilizing said frozen homogenate supernatant to dryness to obtain said mammalian amniotic membrane extract, wherein said quick-freezing step in said lyophilization process is the only freezing step in said method.

2. (Withdrawn/Previously Presented) The method of claim 1, further comprising the step of processing said lyophilized homogenate supernatant to a powder.

3. (Withdrawn/Previously Presented) The method of claim 1, further comprising the step of reconstituting said lyophilized homogenate supernatant.

4. (Withdrawn/Previously Presented) The method of claim 3, wherein said lyophilized homogenate supernatant is reconstituted in a liquid.

5. (Withdrawn/Previously Presented) The method of claim 4, wherein said liquid is selected from the group consisting of balanced salt solution and fresh amniotic fluid.

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6. (Withdrawn/Previously Presented) The method of claim 3, wherein said lyophilized homogenate supernatant is reconstituted in a gel, an ointment, a cream or a soap.

7. (Withdrawn/Previously Presented) The method of claim 1, wherein said amniotic membrane is a human amniotic membrane.

8. (Withdrawn/Currently Amended) The method of claim 1, wherein said amniotic membrane is obtained from a mammal selected from the group consisting of pig, cow ~~or~~ and horse.

9. (Withdrawn/Previously Presented) The method of claim 1, wherein said amniotic membrane is freshly obtained.

10. (Currently Amended) A pharmaceutical composition for prophylaxis and/or treatment of a disease or condition, said composition comprising:

a therapeutically effective amount of a mammalian amniotic membrane extract consisting essentially of a powdered form of a lyophilized mammalian amniotic membrane homogenate supernatant,

reconstituted in a pharmaceutically acceptable carrier for administering said amniotic membrane extract to a patient in need of said prophylaxis and/or treatment, wherein said mammalian amniotic membrane was subjected to only one freezing step during preparation of said extract.

11. (Previously Presented) The pharmaceutical composition of claim 10, wherein said pharmaceutically acceptable carrier is

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selected from the group consisting of an ophthalmic solution for eye drops, a gel, an ointment, an emulsion, a cream, a powder and a spray.

12. (Previously Presented) The pharmaceutical composition of claim 10, wherein said pharmaceutically acceptable carrier comprises a bandage or a medicinal contact lens for local administration to said patient.

13. (Withdrawn/Previously Presented) A method of prophylaxis and/or treatment of a disease or condition, said method comprising the steps of:

providing a patient in need of such prophylaxis and/or treatment; and

administering an effective amount of the pharmaceutical composition of claim 10 to said patient.

14. (Withdrawn/Previously Presented) The method of claim 13, wherein said disease or condition is selected from the group consisting of persistent corneal ulcer, Ocular Cicatritial Pemphigoid, Stevens-Johnson syndrome, conjunctival inflammation, dry eye, Sjögren's syndrome, chemical or thermal injuries, multi-surgery effects, contact lenses over-wear, severe microbial infections, neurotrophic keratitis, ischemic keratitis, peripheral ulcerative or inflammatory keratitis, limbitis aniridia, pterigium or pseudopterygium, and multiple endocrine deficiency.

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15. (Withdrawn/ Previously Presented) The method of claim 13, wherein said carrier in said pharmaceutical composition for said amniotic membrane extract is preservative free eye drops.

16. (Withdrawn/Previously Presented) A kit for prophylaxis and/or treatment of a disease or condition, wherein said kit comprises:

a therapeutically effective amount of the mammalian amniotic membrane extract of claim 20; and

instructions for the use thereof.

17. (Withdrawn/Previously Presented) The kit of claim 16, said kit further comprising a pharmaceutically acceptable carrier for administering said amniotic membrane extract to a patient in need of said prophylaxis and/or treatment.

18. (Withdrawn/Previously Presented) A method of prophylaxis and/or treatment of a disease or condition, said method comprising the steps of:

providing a patient in need of such prophylaxis and/or treatment; and

administering an effective amount of the pharmaceutical composition of claim 11 to said patient.

19. (Withdrawn/Previously Presented) A method of prophylaxis and/or treatment of a disease or condition, said method comprising the steps of:

providing a patient in need of such prophylaxis and/or treatment; and

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administering an effective amount of the pharmaceutical composition of claim 12 to said patient.

20. (Currently Amended) A mammalian amniotic membrane extract consisting essentially of a powdered form of a lyophilized mammalian amniotic membrane homogenate supernatant, wherein said mammalian amniotic membrane was subjected to only one freezing step during preparation of said extract.

21. (Previously Presented) The amniotic membrane extract of claim 20, wherein said amniotic membrane is a human amniotic membrane.

22. (Currently Amended) The amniotic membrane extract of claim 20, wherein said amniotic membrane is from a mammal selected from the group consisting of pig, cow ~~or~~ and horse.

23. (Previously Presented) The pharmaceutical composition of claim 10, wherein said amniotic membrane is a human amniotic membrane.

24. (Currently Amended) The pharmaceutical composition of claim 10, wherein said amniotic membrane is from a mammal selected from the group consisting of pig, cow ~~or~~ and horse.

25. (Withdrawn/Previously Presented) The kit of claim 16, wherein said amniotic membrane is a human amniotic membrane.

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26. (Currently Amended) The kit of claim 16, wherein said amniotic membrane is from a mammal selected from the group consisting of pig, cow ~~or~~ and horse.

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